

MAR 01 2007

Pre-Market Notification 510(k) Summary**1. Sponsor Information:**

Company Name & Address: Velocity Medical Solutions, LLC
1118 Zimmer Drive, Atlanta, GA 30306

Contact Person: Timothy Fox, PhD
Contact Title: President
Contact Phone Number: 404-272-9217
Contact Fax Number: 404-873-8326

Date of Summary: January 24, 2007

2. Device Name and Classification:

Common and Usual Name: Picture Archiving and Communication System
(Medical Imaging Software)

Proprietary Name: VelocityAIS

Classification Name: Image Processing System, Radiology
(21 CFR § 892.2050)

Performance Standards: No applicable performance standards have been issued
under section 514 or under section 513(b) of the Food,
Drug and Cosmetic Act.

3. Predicate Device(s):

GE Medical Systems, Advantage Windows CT/PET Fusion (K010336)
GE Medical Systems, Volume Viewer Plus (K041521)
MIMvista Corp., MIMviewer (K062163)

4. Description of Device:

VelocityAIS is a stand-alone software product that provides medical image processing designed to facilitate the oncology or other clinical specialty work flow by allowing the comparison of medical imaging data from different modalities, points in time, and/or scanning protocols. The product provides users with the means to display, co-register and fuse medical images from multiple modalities including PET, SPECT, CT, and MR, draw Regions of Interest (ROI), calculate, and report relative differences in pixel intensities, Standardized Uptake Value (SUV) or other values within those regions, and import and export results to and from commercially available radiation treatment planning systems and PACS devices.

VelocityAIS is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.

5. Indications for Use:

VelocityAIS is a software package that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. VelocityAIS is not intended for mammography diagnosis.

6. Comparison with Predicate Device(s):

The VelocityAIS is substantially equivalent to the predicate devices (MIMvista Corp MIMviewer , GE Medical Advantage Windows CT/PET Fusion and GE Medical Volume Viewer Plus). VelocityAIS is similar in characteristics, materials, features, has similar technological features, intended use and indications for use as the predicates, and does not pose any new issues of safety and effectiveness.

7. Non-Clinical Performance Summary:

Velocity Medical Solutions has verified and validated that the VelocityAIS software meets its functional specifications and performance requirements.

8. Conclusions:

In summary, Velocity Medical Solutions, LLC, is of the opinion that the VelocityAIS does not introduce any new potential safety risks, is as effective, and performs as well as devices currently on the market, and concludes that the VelocityAIS is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Velocity Medical Solutions, LLC
% Mr. Paul Summer
Director, Regulatory & Quality Systems
ARKIN Consulting Group
1733 Canton Lane
MARIETTA GA USA 30062

MAR 01 2007

Re: K070248
Trade/Device Name: VelocityAIS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systeme
Regulatory Class: II
Product Code: LLZ
Dated: January 24, 2007
Received: January 25, 2007

Dear Mr. Summer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

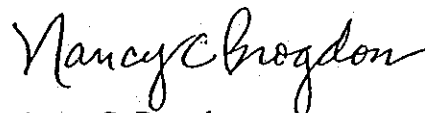
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K070248

Device Name: VelocityAIS

Indications For Use:

VelocityAIS is a stand-alone software product that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. VelocityAIS is not intended for mammography diagnosis.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

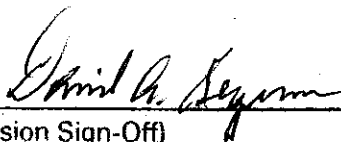
~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K070248